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10/536,542	05/26/2005	Roger Petrus Gerebern Vandecruys	JANS-0086 / PRD2017USPCT	7079

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EXAMINER	
VU, JAKE MINH	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
07/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

Office Action Summary	Application No.	Applicant(s)	
	10/536,542	VANDECRUYS ET AL.	
	Examiner	Art Unit	
	JAKE M. VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-67* is/are pending in the application.

4a) Of the above claim(s) *43-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the Appeal Brief filed on 04/14/2010, PROSECUTION IS HEREBY REOPENED. However, new grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

- Claims 21-67 are pending in the instant application.
- Claims 43-67 have been previously withdrawn from consideration.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of U.S. Patent No. 7,241,458.

CHEN2 teaches a composition comprised of: an antiviral drugs, such as viral protease inhibitors (see abstract) or formula I in the amount of 1% (see col. 9, line 24-27); organic polymer, such HPMC (see col. 15, line 20); antioxidants, such 1% citric acid (see col. 17, line 43-45); surfactants, such as sodium lauryl sulfate and Vitamin E-TPGS (see col. 15, line 45-60), wherein the surfactants improves the dispersion and dissolution of the drug (see col. 15, line 45-46); solid dispersion (see abstract); solid, semi solid, and tablet (see col. 16, line 57-65), which would read on adapted for the mouth; lactose (see col. 15, line 22), which is a bulking agents.

CHEN2 does not teach using an antiviral, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile; or the amount of ingredients as claimed by Applicant.

Patent '458 recites a particle or solid dispersion consisting of: a compound of formula I-A (see claim 1 and 11), which is a structural analogue of Applicant's 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino-]benzonitrile compound; and a pharmaceutically acceptable water-soluble polymer (see claim 1 and 11). Patent '458 does not recite the exact 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino-]benzonitrile compound. However, Patent '458 disclosed 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino-]benzonitrile compound (see col. 13, line 25).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile into CHEN2's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because it would improve the dissolution and dispersion of the drug and both drugs are functional equivalent drugs used as antiviral drugs. The person of ordinary skill in the art reasonably would have expected success because both reference dealt with the same field of endeavor, such as pharmaceutical drugs.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely

optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as drug release rate or dissolution of the drug. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Claims 21-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of U.S. Patent No. 7,037917.

CHEN2 teaches a composition comprised of: an antiviral drugs, such as viral protease inhibitors (see abstract) or formula I in the amount of 1% (see col. 9, line 24-27); organic polymer, such HPMC (see col. 15, line 20); antioxidants, such 1% citric acid (see col. 17, line 43-45); surfactants, such as sodium lauryl sulfate and Vitamin E-TPGS (see col. 15, line 45-60), wherein the surfactants improves the dispersion and dissolution of the drug (see col. 15, line 45-46); solid dispersion (see abstract); solid, semi solid, and tablet (see col. 16, line 57-65), which would read on adapted for the mouth; lactose (see col. 15, line 22), which is a bulking agents.

CHEN2 does not teach using an antiviral, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile; or the amount of ingredients as claimed by Applicant.

Patent '779 recites a method of treating HIV infection comprising administering a 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino-]benzonitrile compound (see claim 1).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile into CHEN2's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because it would improve the dissolution and dispersion of the drug and both drugs are functional equivalent drugs used as antiviral drugs. The person of ordinary skill in the art reasonably would have expected success because both reference dealt with the same field of endeavor, such as pharmaceutical drugs.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as drug release rate or dissolution of the drug. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Claims 21-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of U.S. Patent No. 6,878,717.

CHEN2 teaches a composition comprised of: an antiviral drugs, such as viral protease inhibitors (see abstract) or formula I in the amount of 1% (see col. 9, line 24-27); organic polymer, such HPMC (see col. 15, line 20); antioxidants, such 1% citric acid (see col. 17, line 43-45); surfactants, such as sodium lauryl sulfate and Vitamin E-TPGS (see col. 15, line 45-60), wherein the surfactants improves the dispersion and dissolution of the drug (see col. 15, line 45-46); solid dispersion (see abstract); solid, semi solid, and tablet (see col. 16, line 57-65), which would read on adapted for the mouth; lactose (see col. 15, line 22), which is a bulking agents.

CHEN2 does not teach using an antiviral, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile; or the amount of ingredients as claimed by Applicant.

Patent '717 recites a compound of formula I (see claim 1), which is the genus of compounds and includes 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino-]benzonitrile. Patent '717 disclosed 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino-]benzonitrile (see col. 8, line 38).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile into CHEN2's composition. The person of ordinary skill in the art would have been motivated to make those

modifications, because it would improve the dissolution and dispersion of the drug and both drugs are functional equivalent drugs used as antiviral drugs. The person of ordinary skill in the art reasonably would have expected success because both reference dealt with the same field of endeavor, such as pharmaceutical drugs.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as drug release rate or dissolution of the drug. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Claims 21-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter “CHEN2") in view of copending Application No. 11/930,835.

CHEN2 teaches a composition comprised of: an antiviral drugs, such as viral protease inhibitors (see abstract) or formula I in the amount of 1% (see col. 9, line 24-27); organic polymer, such HPMC (see col. 15, line 20); antioxidants, such 1% citric acid (see col. 17, line 43-45); surfactants, such as sodium lauryl sulfate and Vitamin E-

TPGS (see col. 15, line 45-60), wherein the surfactants improves the dispersion and dissolution of the drug (see col. 15, line 45-46); solid dispersion (see abstract); solid, semi solid, and tablet (see col. 16, line 57-65), which would read on adapted for the mouth; lactose (see col. 15, line 22), which is a bulking agents.

CHEN2 does not teach using an antiviral, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile; or the amount of ingredients as claimed by Applicant.

Application '835 recites a 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino-]benzonitrile compound (see claim 31).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile into CHEN2's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because it would improve the dissolution and dispersion of the drug and both drugs are functional equivalent drugs used as antiviral drugs. The person of ordinary skill in the art reasonably would have expected success because both reference dealt with the same field of endeavor, such as pharmaceutical drugs.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in th e art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It

would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as drug release rate or dissolution of the drug. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

This is a provisional obviousness-type double patenting rejection.

Claims 21-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of copending Application No. 11/733,507.

CHEN2 teaches a composition comprised of: an antiviral drugs, such as viral protease inhibitors (see abstract) or formula I in the amount of 1% (see col. 9, line 24-27); organic polymer, such HPMC (see col. 15, line 20); antioxidants, such 1% citric acid (see col. 17, line 43-45); surfactants, such as sodium lauryl sulfate and Vitamin E-TPGS (see col. 15, line 45-60), wherein the surfactants improves the dispersion and dissolution of the drug (see col. 15, line 45-46); solid dispersion (see abstract); solid, semi solid, and tablet (see col. 16, line 57-65), which would read on adapted for the mouth; lactose (see col. 15, line 22), which is a bulking agents.

CHEN2 does not teach using an antiviral, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile; or the amount of ingredients as claimed by Applicant.

Application '507 recites a 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino-]benzonitrile compound (see claim 32).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile into CHEN2's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because it would improve the dissolution and dispersion of the drug and both drugs are functional equivalent drugs used as antiviral drugs. The person of ordinary skill in the art reasonably would have expected success because both reference dealt with the same field of endeavor, such as pharmaceutical drugs.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as drug release rate or dissolution of the drug. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

This is a provisional obviousness-type double patenting rejection.

Claims 21-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of copending Application No. 11/204,513.

CHEN2 teaches a composition comprised of: an antiviral drugs, such as viral protease inhibitors (see abstract) or formula I in the amount of 1% (see col. 9, line 24-27); organic polymer, such HPMC (see col. 15, line 20); antioxidants, such 1% citric acid (see col. 17, line 43-45); surfactants, such as sodium lauryl sulfate and Vitamin E-TPGS (see col. 15, line 45-60), wherein the surfactants improves the dispersion and dissolution of the drug (see col. 15, line 45-46); solid dispersion (see abstract); solid, semi solid, and tablet (see col. 16, line 57-65), which would read on adapted for the mouth; lactose (see col. 15, line 22), which is a bulking agents.

CHEN2 does not teach using an antiviral, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile; or the amount of ingredients as claimed by Applicant.

Application '513 recites a method for inhibiting reverse transcriptase comprising administering a 4-[[4-amino-5-chloro-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]benzonitrile compound (see claim 23).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile into CHEN2's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because it would improve the dissolution and dispersion of the drug and

both drugs are functional equivalent drugs used as antiviral drugs. The person of ordinary skill in the art reasonably would have expected success because both reference dealt with the same field of endeavor, such as pharmaceutical drugs.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as drug release rate or dissolution of the drug. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-29, 31, 32, 34-42 are rejected under 35 U.S.C. 102(a,e) as being anticipated by CHEN et al (6,919,370; hereinafter "CHEN1") as evidence by FAIS et al (US 2008/0160106) and CASODEX (Drug Information at http://www.rxlist.com/casodex-drug.htm (2009)).

Applicant's claims are directed to a composition comprising of: a basic drug compound; vitamin E-TPGS; water-soluble acid, such as citric acid, wherein the acid:drug ratio is at least 1:1 by weight; organic polymer, such as polyalkylene oxide or poloxomers. Additional limitations include: intimately admixed; solid dispersion; bulking agents; adapted for the mouth.

CHEN teaches a composition comprised of: a basic and water-insoluble drug compound, such as paclitaxel (see col. 20, line 32 and Title) or other cancer drugs, such as cisplatin and bicalutamide (see col. 7, line 8-23); vitamin E-TPGS (see col. 20, line 33); water-soluble acid, such as citric acid (see col. 20, line 36), wherein the acid:drug ratio is 0.1-1%:0.1-1% (see col. 20, Example 11), which reads on at least 1:1 by weight; organic polymer, such as polysorbate 20 (see col. 20, line 34), which is an polyalkylene oxide, or poloxamers (see col. 23, line 56). Additional disclosures include: mixture (see col. 3, line 58), which would read on intimately admixed; tablet, suspension, which would read on solid dispersion, gels and semi-solid containing the active can be prepared according to well-known methods (see col. 16, line 2-16); fillers (see col. 21, line 8), which would read on bulking agents; oral (see col. 21, line 21), which would read adapted for the mouth; amount of Vitamin E-TPGS could be 1-94% (see col. 20,

Example 11) of the composition; the "paclitaxel solubilizers", such as PEG-Vitamin E (see col. 7, line 13-15), which is Vitamin E-TPGS (see col. 11, line 48-66) can replace the disadvantageous excipient Cremophor EL as a solubilizing excipient (see col. 3, line 57-67).

Note, the viscosity is an inherent property of the polymer; thus, the polymer of the prior art must have the same viscosity as claimed by Applicant, since it is the same polymer as claimed by Applicant.

FAIS disclosed that cisplatin is a weak basic drug (see [103]).

CASODEX disclosed that bicalutamide has a pKa value of 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over VERRECK et al (WO 01/22938) in view of CHEN et al (US 6,828,301) and CLANCY et al (WO 97/02017) **are withdrawn**.

However, upon further consideration, a new ground(s) of rejection is made as discussed below.

Claims 21-29, 31, 32, 34-42 are rejected under 35 U.S.C. 102(a,e) as being anticipated by CHEN1 et al (6,919,370; hereinafter "CHEN1") as evidence by FAIS et al (US 2008/0160106) and CASODEX (Drug Information at http://www.rxlist.com/casodex-drug.htm (2009)).

As discussed above, CHEN teaches a composition comprised of: a basic and water-insoluble drug compound, such as paclitaxel (see col. 20, line 32 and Title) or other cancer drugs, such as cisplatin and bicalutamide (see col. 7, line 8-23); vitamin E-TPGS (see col. 20, line 33); water-soluble acid, such as citric acid (see col. 20, line 36), wherein the acid:drug ratio is 0.1-1%:0.1-1% (see col. 20, Example 11), which reads on at least 1:1 by weight; organic polymer, such as polysorbate 20 (see col. 20, line 34), which is an polyalkylene oxide, or poloxamers (see col. 23, line 56). Additional disclosures include: mixture (see col. 3, line 58), which would read on intimately admixed; tablet, suspension, which would read on solid dispersion, gels and semi-solid containing the active can be prepared according to well-known methods (see col. 16, line 2-16); fillers (see col. 21, line 8), which would read on bulking agents; oral (see col. 21, line 21), which would read adapted for the mouth; amount of Vitamin E-TPGS could be 1-94% (see col. 20, Example 11) of the composition; the "paclitaxel solubilizers", such as PEG-Vitamin E (see col. 7, line 13-15), which is Vitamin E-TPGS (see col. 11, line 48-66) can replace the disadvantageous excipient Cremophor EL as a solubilizing excipient (see col. 3, line 57-67). FAIS disclosed that cisplatin is a weak basic drug (see [103]). CASODEX disclosed that bicalutamide has a pKa value of 12.

CHEN1 does not teach an example having cisplatin or bicalutamide as the cancer drug.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate bicalutamide as the cancer drug in CHEN's composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because CHEN suggested using other cancer drugs, such as cisplatin or bicalutamide.

Note, the viscosity is an inherent property of the polymer; thus, the polymer of the prior art must have the same viscosity as claimed by Applicant, since it is the same polymer as claimed by Applicant.

Claims 21-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of VERRECK et al (WO 01/22938).

Applicant's claims are directed to a composition comprising of: an antiviral compound, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile; vitamin E-TPGS, which is a surfactant; water-soluble acid, such as citric acid, wherein the acid:drug ratio is at least 1:1 by weight; organic polymer, such as hydroxypropyl methylcellulose (herein after "HPMC"). Additional limitations include: intimately admixed; solid dispersion; adapted for the mouth bulking agents; tablet.

CHEN2 teaches a composition comprised of: an antiviral drugs, such as viral protease inhibitors (see abstract) or formula I in the amount of 1% (see col. 9, line 24-27); organic polymer, such HPMC (see col. 15, line 20); antioxidants, such 1% citric acid (see col. 17, line 43-45); surfactants, such as sodium lauryl sulfate and Vitamin E-TPGS (see col. 15, line 45-60), wherein the surfactants improves the dispersion and dissolution of the drug (see col. 15, line 45-46); solid dispersion (see abstract); solid, semi solid, and tablet (see col. 16, line 57-65), which would read on adapted for the mouth; lactose (see col. 15, line 22), which is a bulking agents.

CHEN2 does not teach using an antiviral, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile; or the amount of ingredients as claimed by Applicant.

VERRECK teaches a composition comprising of: an antiviral drug, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile (see pg. 17, line 8-9), which is an antiviral drug; sodium lauryl sulfate (see pg. 42, line 28); water-soluble acid, such as citric acid (see pg. 10, line 5-6); organic polymer, such as HPMC (see pg. 36, line 1). Additional limitations include: mixture (see pg. 1, line 8), which would read on intimately admixed; solid dispersion (see pg. 40, line 4); tablet (see pg. 41, line 30), which would read on adapted for the mouth; diluent and fillers (see pg. 42, line 10), which would read on bulking agents; advantageous dissolution properties (see pg. 38, line 14); compounds with faster dissolution rate is preferred (see pg. 39, line 36-37); and a dissolution study of dissolved drugs (see pg. 76, line 4-25).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile into CHEN2's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because it would improve the dissolution and dispersion of the drug and both drugs are functional equivalent drugs used as antiviral drugs. The person of ordinary skill in the art reasonably would have expected success because both reference dealt with the same field of endeavor, such as pharmaceutical drugs.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as drug release rate or dissolution of the drug. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Note, the viscosity is an inherent property of the polymer; thus, the polymer of the prior art must have the same viscosity as claimed by Applicant, since it is the same polymer as claimed by Applicant.

Telephonic Inquiries

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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